



DEPARTMENT OF HEALTH & HUMAN SERVICES

95132d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: FEI 3000203397

December 17, 2004

Jeffrey R. Aivazian, President
The Meat Market, Inc.
454 West Alluvial Avenue
Fresno, California 93650

WARNING LETTER

Dear Mr. Aivazian:

On September 9 and 13, 2004, we inspected your seafood processing facility, The Meat Market, Inc., located at 454 Alluvial Avenue, Fresno, California. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, or to otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your refrigerated Mahi Mahi, tuna, and refrigerated, ready-to-eat crab are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation, and the Food and Drug Administration's (FDA) Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001, through links in FDA's home page at www.fda.gov.

Your serious deviations were as follows:

1. You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product that you process, and you must have and implement a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for refrigerated, ready-to-eat crab to control the food safety hazard of pathogen growth and toxin formation as a result of time/temperature abuse (i.e., exposure to unsafe temperatures) during the thawing and refrigerated storage of this product.

2. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR 123.3(f) as "any biological, chemical, or physical property that may cause food to be unsafe for human consumption." However, your firm's HACCP plan for "Salmon, Chilean Sea Bass, New England Sole, Stuffed Sole, Catfish, Stripped Sea Bass, English Sole, Halibut, Red Snapper, Swordfish, Petralli Sole, Orange Roughy, Trout, Fillet of Sole, John Dory, Mahi-Mahi, Ahi Tuna" does not list the food safety hazard of histamine formation for the refrigerated scombroid species (Mahi mahi and Ahi tuna) as a result of time/temperature abuse at the Receiving and Storage critical control points. Chapter 7 of the Fish & Fisheries Products Hazards & Controls Guide can provide guidance with regards to appropriate critical limits, monitoring procedures, corrective action, and verification procedures applicable to your seafood operations.

You must immediately take appropriate steps to correct the violations. We may take further action if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of your revised HACCP plans, HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation, and the Current Good Manufacturing Practices (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your response should be directed to: Ms. Erlinda N. Figueroa, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

C. D. Moss Acting DD

for Barbara J. Cassens
District Director
San Francisco District